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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/858,318	05/15/2001	Gregory J. Kellogg	95.1408-GGG	3092

20306 7590 07/13/2004

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EXAMINER	
CROSS, LATOYA I	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/858,318	KELLOGG ET AL.	
	Examiner	Art Unit	
	LaToya I. Cross	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *25-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24 and 33-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9-4-02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed September 4, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. A copy of the non-patent literature document (Brody et al) was not submitted with the IDS. Applicants are requested to submit the reference so that the Examiner may consider it.

Election/Restrictions

2. Applicant's election with traverse of group I, claims 1-24 and 33-41 in the reply filed on April 16, 2004 is acknowledged. The traversal is on the ground(s) that it would not be an undue burden on the Examiner to examiner all of the claims together. This is not found persuasive because as pointed out in the Restriction, the groups of claims do not require the same search. Thus, prior art the Examiner finds for the claims of group I may not read on the group II claims. Such would require the Examiner to conduct further searches for the apparatus of group II, which would indeed be burdensome.

The requirement is still deemed proper and is therefore made FINAL.

Claim Observations

- Claim 11 contains the phrase "the mixing microchannel". There is no antecedent basis for this phrase. It is suggested that claim 11 be amended to be dependent on claim 8.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claim1-24 and 33-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-20 and 29-37 of U.S. Patent No. 6,582,662 to Kellogg et al in view of US Patent 6,063,589 to Kellogg et al. The Kellogg et al '62 patent contains claims directed to a microsystems platform comprising a rotatable platform having a substrate with microfluidic structures wherein the microfluidic structures comprise reagent reservoirs, sample reservoirs, a collection chamber (detection chamber) and a mixing microchannel, wherein microchannels fluidly connect all of the chambers and reservoirs. The '662 patent also contains claims directed to a method of homogenous mixing and a method for performing biological reactions. The claims of the instant invention comprise the same rotatable platform having the same microfluidic structures. The claims of the instant invention also recite the same methods of mixing and biological reaction. The instant invention differs only in the addition of a reagent aliquotting manifold, bulk reagent chambers and an overflow reservoir. Kellogg et al '589 teaches such a reagent aliquotting manifold, with a bulk reagent reservoir and an overflow chamber in a microsystem platform to allow imprecise amounts of

reagent to enter the system while causing precise amounts of reagent to be delivered to the various chambers by rotational forces. It would have been obvious to one of ordinary skill in the art to incorporate a reagent manifold, with a reagent reservoir and overflow chamber into the microsystem platform of the '662 patent to provide a device that allow distribution of fluids throughout the system without needing initial precise measurements.

5. Claims 1-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/746,821 in view of US Patent 6,063,589 to Kellogg et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application has claims directed to a microsystem platform comprising sample reservoirs, an overflow reservoir, diluent reservoirs (reagent reservoir), a metering manifold (reagent manifold) and microchannels that connect all of the chambers and reservoirs. The instant application is different from the copending application only in the addition of detection chambers. Kellogg et al '569 teach the use of detection chambers to allow the sample to be analyzed while moving throughout the device. It would have been obvious to one of ordinary skill in the art to incorporate detection chambers into the device of the '821 application to provide analysis means in the device and allow the sample to be analyzed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 37 and 38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,709,869 to Mian et al in view of US Patent 6,063,589 to Kellogg et al. Mian et al contains claims directed to a

method for biological detection using a microsystem platform having sample chambers, reagent reservoirs, detection chambers and microchannels fluidly connecting all of the chambers and reservoirs. The claims of the invention recite the same method of biological detection using a microsystem platform, differing only in the presence of a reagent manifold with an overflow chamber and a reagent reservoir. Kellogg et al '569 teach such a reagent aliquotting manifold, with a bulk reagent reservoir and an overflow chamber in a microsystem platform to allow imprecise amounts of reagent to enter the system while causing precise amounts of reagent to be delivered to the various chambers by rotational forces. It would have been obvious to one of ordinary skill in the art to incorporate a reagent manifold, with a reagent reservoir and overflow chamber into the microsystem platform of the '662 patent to provide a device that allow distribution of fluids throughout the system without needing initial precise measurements.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-8, 11, 14-16, 33-39 are rejected under 35 U.S.C. 102(b) as being anticipated by European publication 0 608 006 to Abaxis, Inc.

Abaxis teaches analytical rotors which are microsystem platforms that use centripetal force to move micro volumes of fluids throughout the device. As shown in figure 1, the circular disk device comprises a blood application (sample application) port (22), which serves as a reservoir into which a blood sample enters. The device also comprises a metering chamber (40)

into which blood flows via an inlet segment (42). The metering chamber separates the "bulk" fluid into an exact amount and an excess amount, wherein the excess amounts flows to an overflow chamber (44). The exact amount of fluid needed is that amount which remains in the metering chamber after the excess has flowed to the overflow chamber. The device further comprises a reagent chamber (80) and a detection chamber (92). All of the chambers are fluidly connected to one another by way of microchannels (42, 46, 70, 82, 94). An embodiment of the shown in figures 22-24 comprises a blood metering chamber (316) and a diluent (reagent) metering chamber (306). The diluent metering chamber has bulk diluent reservoir (304) and an overflow chamber (310) with a connecting channel (312). The bulk diluent reservoir is equivalent to Applicants' claimed bulk reagent reservoir, while the diluent metering chamber is equivalent to Applicants' claimed reagent aliquotting manifold because the diluent metering chamber provides an exact amount of diluent in the chamber and causes excess diluent to flow to the overflow chamber. Further, a mixing chamber may be included, wherein the mixing chamber is connected to the sample chamber and diluent chamber. With respect to claim 2, the entry (22) serves a sample inlet for the blood sample. With respect to claim 3, the opening to the reagent chamber serves as a reagent inlet. With respect to claim 4, 15 and 16, Abaxis teaches that each of the layers of the device is composed of transparent plastic (col. 14, lines 41-43). With regard to the capacity of the reservoirs, the reference teaches that the metering chamber (either sample or reagent metering chamber) has a volume of 0.005-0.05 cc (5000-50000 nL), as recited in claims 5 and 6. The reference further teaches that the volume of the detection wells is about 0.005-0.015 cc (5000-15000 nL). See col. 16, lines 16-24 and col. 17, lines 42-45. with regard to claim 11, Abaxis teaches that spinning of the rotor causes a radially outward flow of the biological fluid though the device. The rotor is spun at a rate of 1500-5000

rpm for a time ranging from 20 seconds to five minutes. With regard to the method of claims 33-39, Abaxis teaches that a sample is introduced into the rotor device along with reagents and diluents in respective reagent and diluent chambers. The rotor is spun to allow the sample to pass via the channels between the chambers. The reference teaches spinning at a lower speed, followed by rapid acceleration (col. 24, lines 29-36).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1-24, 33-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,582,662 to Kellogg et al in view of US Patent 6,063,589 to Kellogg et al (hereinafter referred to as Kellogg et al '662 and Kellogg et al '589).

Kellogg et al '662 teach a microsystem platform device for performing miniaturized assays. The device has a disc shape comprising a reservoir layer (201) and a microfluidics layer (301). The reservoir layer (201) comprises fluid chambers (205, 206, 207) for inner ring assays

and fluid chambers (208, 209, 210) for outer ring assays. The fluid chambers may contain sample or reagents. Detection chambers (211, 212) are also provided, as well as air outlet ports air displacement holes (214). See figure 3 and col. 4, lines 52-67. Figure 5 shows the details of the microfluidics. Microchannels (305, 306), cap junctions (309, 314) and mixing microchannels (308) are disposed in the microfluidics layer of the device. With respect to claims 5-7, the fluid reservoirs have a volume of 1 nL to about 1 mL (col. 5, lines 35-37; col. 18, lines 37-45). The microchannels have a size ranging from 0.1 um to about 1 mm, a thickness of about 0.1mm to 25 mm, wherein the cross sectional dimension of the microchannels across the thickness dimension of the platform is less than 1 mm, and can be from 1-90% of the cross sectional dimension of the platform, as recited in claim 18. Regarding claims 15-16, the disk is fabricated from materials, such as plastic (col. 13, lines 38-41). The mixing microchannels have a length of 1mm – 100mm and are comprised of multiple bends as shown in the figures, as recited in claims 8 and 9 (col. 21, lines 27-30). Further, Kellogg et al '662 teach fluid flow rates of about 1 nL – 1000 nL using rotational speeds of 4-30,000 rpms (col. 17, lines 42-44), as recited in claims 11-13. With respect to the number of microfluidic structures, figures 4 and 5 show 48 structures repeated with angular spacing of 7.5°. Regarding the diameter of the disc, Kellogg et al '662 teach 10-50 mm (col. 17, lines 61-67). With respect to the method for mixing a sample and reagents or analyzing a sample, Kellogg et al '662 teach applying a sample to a sample reservoir, apply a reagent to a reagent reservoir, rotating the platform at sufficient speed to move the fluid between the various reservoirs.

Kellogg et al '662 differs from the instant invention in that it fails to teach the claimed bulk reagent reservoirs, overflow reservoir and reagent manifold.

Kellogg et al '589 teach microsystem platforms like those disclosed by Kellogg et al '662. Kellogg et al '589 further teaches using a metering capillary to allow an imprecise amount of reagent to be applied to the system, but which will provide an exact amount of reagent for analysis. Specifically, as shown in figure 3A of Kellogg et al '589, a reagent reservoir (bulk), 201, is coupled to a metering capillary (202), which in turn is coupled to an overflow chamber and a holding chamber. An imprecise amount of fluid enters into the bulk reservoir (201). The fluid flows into the metering device (202). Excess fluid flows to the overflow chamber (205) via overflow capillary (203). The exact amount of fluid needed (that amount remaining after the excess has flowed to the overflow chamber) remains in the metering chamber which flows to the holding chamber and used in the analysis.

It would have been obvious to one of ordinary skill in the art to use a metering device, such as disclosed by Kellogg et al '589 in the device of Kellogg et al '662 to alleviate the need for precise measurements of the reagents and to allow reagent to be distributed to a plurality of components simultaneously.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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